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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,888	12/21/2001	William Canfield	203515US77	5416

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/22/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/023,888

Applicant(s)

CANFIELD ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 23-25, 27 and 38-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22, 26 and 28-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-55 are pending.

#### ***Election/Restriction***

Applicant's election with traverse of Group III, claims 22, 26 and 28-37, drawn to a GlcNAc phosphotransferase, in Paper No. 9 filed March 27, 2003 is acknowledged. The traversal is on the ground(s) that "the Office has not shown that a burden exists in searching the entire application". Applicants continue "a search of all claims would not constitute a serious burden on the Office" (page 2). This is not found persuasive because proteins and nucleic acids are different compounds each with its own chemical structure and function, and they have different utilities. A DNA molecule can be used for the production of an encoded enzyme and as a hybridization probe. An enzyme can be obtained by a materially different method such as by the biochemical purification. Furthermore, the examination of nucleic acids with proteins would require a diverse consideration and an additional search of at least 435/252.3, 320.1; 536/23.2.

It is noted that "Applicant requests that upon finding that the elected group is allowable, the corresponding non-elected process claims be rejoined" (page 2). The rejoinder will be considered at the time the elected group is found allowable.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 1-21, 23-25, 27 and 38-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups I, II and IV-VII, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 is directed to a polypeptide of SEQ ID NO:2. The specification states that "The soluble GlcNAc-phosphotransferase protein or polypeptide as used herein is understood to mean the sequences exemplified in this application as well as those which have substantial identity to SEQ ID NO:2" (page 10, lines 15-17). From this description is unclear what SEQ ID NO:2 represents, i.e., is it naturally occurring or artificial sequence. In the latter case, it is not described what are the constitutive parts thereof such that, for example, residues 1-900 of SEQ ID NO:2 are identical to  $\alpha$

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subunit of human GlcNAc phosphotransferase, residues 901-910 are residues comprising Furin cleavage site, residues 911- 1199 are identical to  $\beta$  subunit of human GlcNAc phosphotransferase, etc.

Claims 26 and 28-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 26 and 28-37 are directed to an GlcNAc-phosphotransferase comprising  $\alpha$  and  $\beta$  subunits and not endogenous proteolytic cleavage site between them. Therefore, the claims are directed to a genus of GlcNAc-phosphotransferases comprising subunits from any source both naturally occurring and man made having any structure. The subunits encompass polypeptides of unknown function and structure with any stoichiometry between subunits. The specification teaches the structure of only a single representative species of such GlcNAc-phosphotransferases, the GlcNAc-phosphotransferase having the amino acid sequence of SEQ ID NO:2. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being GlcNAc-phosphotransferase. Furthermore, with regard to  $\alpha$  and  $\beta$  subunits the specification, the specification teaches the structure of only a single representative species of each

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subunit having the amino acid sequences of SEQ ID NO: 4 and 5, respectively. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of being " $\alpha$  and  $\beta$  subunits" and fails to provide any structure:function correlation present in all members of the claimed genus. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

The claims reciting the specific sequence of one subunit are included in this rejection because the second subunit is not described by the specific sequence.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30, 33 and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-30 and 33 recite "stringent conditions". As described in the specification and known in the art, these conditions "will be different in different circumstances" rendering the metes and bounds of the claims unascertainable (page 12, lines 11-19).

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Claim 30 is confusing as dependent from itself. For the purposes of this examination it was construed as dependent from claim 26.

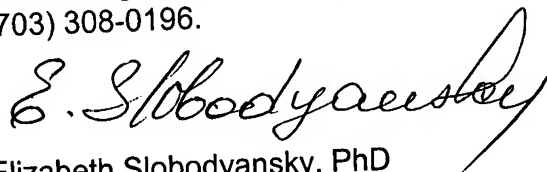
Claims 35-37 recite various proteolytic cleavage sites. It is unclear which amino acid sequences other than SEQ ID NOs:22-25 correspond to each of these sites. Specifically, it is unclear which amino acid sequences other than SEQ ID NO:25 correspond to "Genease I proteolytic cleavage site" (emphasis added).

Claim 37 is confusing as stating that "Furin proteolytic cleavage site comprises SEQ ID NO:22", whereas SEQ ID NO:22 is Ile-Glu-Gly-Arg, i.e. the cleavage site of Factor Xa.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD  
Primary Examiner

April 16, 2003